

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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JOSEPH COLELLA, individually and
on behalf of other similarly
situated persons,

MEMORANDUM AND ORDER

17-cv-5867 (KAM)

Plaintiff,

-against-

ATKINS NUTRITIONALS, Inc.,

Defendant.

-----x

MATSUMOTO, United States District Judge:

Plaintiff Joseph Colella, ("plaintiff" or "Colella"), brings this action against defendant Atkins Nutritionals, Inc ("defendant" or "Atkins Nutritionals") alleging violations of N.Y. Gen. Bus. Law ("NYGBL") §§ 349 and 350 in connection with defendant's alleged misleading labeling of its Atkins line of food products. (See ECF No. 1, Complaint ("Compl."); ECF No. 26, Amended Complaint ("Am. Compl.").) In the Amended Complaint, plaintiff seeks declaratory relief, injunctive relief, actual damages, statutory damages, punitive damages, restitution, disgorgement and attorneys' fees and costs. (See Am. Compl. at 22.)

I. Background

a. Procedural Background

Plaintiff's counsel has filed putative class action lawsuits in federal courts in New York, California and Missouri. In the putative class actions, the plaintiffs alleged that defendants misleadingly labeled their products as having low or no Net Carbs, despite the presence of sugar alcohols, which plaintiff alleges affect blood sugar levels, contrary to the claims on the Atkins Nutritionals products packaging. *See Smith v. Atkins Nutritionals, Inc.*, No. 18-CV-04004, Doc. 19 (W.D. Mo. May 8, 2018); *Fernandez v. Atkins Nutritionals, Inc.*, No. 3:17-CV-1628, 2018 WL 280028 (S.D. Cal. Jan. 3, 2018); *Johnson v. Atkins Nutritionals, Inc.*, No. 2:16-CV-4213, 2017 WL 6420199 (W.D. Mo. Mar. 29, 2017); *Colella v. Atkins Nutritionals, Inc.*, 17-CV-5867 (E.D.N.Y.).

On October 6, 2017, plaintiff filed his putative class action Complaint. (See ECF No. 1, Compl.) On February 8, 2018, after a pretrial conference, plaintiff amended the complaint. (ECF No. 26, Am. Compl.) On April 9, 2018, defendant filed a motion to dismiss pursuant to Federal Rules of Civil Procedure Rule 12(b)(6) on the bases that (1) plaintiff's state law claims related to Atkin Nutritionals' quantitative Net Carbs claims and calculation method are preempted by federal law, (2) plaintiff's claims should be dismissed pursuant to the primary jurisdiction

doctrine, (3) plaintiff' claims should be dismissed for failure to satisfy the pleading requirements of Fed. R. Civ. P. 8, (4) plaintiff fails to adequately allege injury for his NY General Business Law claims, (5) plaintiff's breach of warranty claims should be dismissed as plaintiff failed to provide defendant with notice, and (6) plaintiff lacks standing to seek injunctive relief. (ECF No. 27-1, Memorandum in Support of Motion to Dismiss ("Def. Mem."), at 7-9.)¹ By letters filed October 12, 2018 and November 2, 2018, defendant provided the court with supplemental authority supporting its Motion to Dismiss. (See ECF No. 35, Defendant's Supplemental Authority Letter; ECF No. 37, Plaintiff's Supplemental Authority Letter.) For the following reasons, the defendant's motion to dismiss is granted in part and denied in part.

b. Factual Background

Plaintiff, in the Amended Complaint, alleges that Atkins Nutritionals' labeling of Net Carbs on its food products is "false, misleading, and likely to deceive consumers." (Am. Compl. ¶¶ 1, 51.) The three labeling claims that plaintiff alleges are false, misleading and likely to deceive consumers are (1) the use of the phrase "Xg Net Carbs" while excluding

¹ Page citations referenced herein refer to the numbers assigned by the Electronic Court Filing System ("ECF") except where specifically noted that a documents internal numbering system will be utilized.

sugar alcohols, (2) the use of the phrase "Only Xg Net Carbs," and (3) Atkins Nutritionals "Counting Carbs" label, which explains the calculation method for Net Carbs and states that sugar alcohols "minimally impact blood sugar." (*Id.* ¶¶ 53-55.) Plaintiff alleges that the claims are false, misleading and likely to deceive because Atkins Nutritionals claims that sugar alcohols "minimally impact blood sugar", but sugar alcohols are proven to "have a significant impact on blood sugar levels." (*Id.* ¶¶ 3, 30-32.) Atkins Nutritionals' website allegedly explains that the calculation of Net Carbs is based on science and reflects "the total carbohydrate content of the food minus the fiber content and sugar alcohols." (*Id.* ¶¶ 16-17.)²

Plaintiff alleges that the Atkins Nutritionals website also states:

Net Carbs are the carbohydrates that significantly impact the blood-sugar level; they're the only carbs that count when following Atkins. The good news is that the grams of carbohydrate in fiber, glycerine, and sugar alcohols don't break down and convert to blood sugar and need not be counted by people on the ANA. . . . So Net Carbs represent the number of grams of total carbohydrate minus those that do not impact blood sugar.

(*Id.* ¶ 18.)

² Plaintiff alleges that the claims regarding Net Carbs made on the Atkins Nutritionals website were removed after litigation commenced, but can be found using the Internet Wayback Machine, an online archiving website. (*Id.* ¶ 18, n. 1 (citing Atkins' Nutritionals, *The Blood Sugar Roller Coaster*, <https://web.archive.org/web/20140930191256/http://www.atkins.com/Science/Articles---Library/Carbohydrates/The-Blood-Sugar-Roller-Coaster--Excess-Carbs,-Exce.aspx> (last visited December 7, 2018)).)

According to plaintiff, however, Atkins Nutritionals' claims are contradicted by science. Dr. Atkins originally rejected the use of sugar alcohols on the Atkins Diet, and other scientists have refuted Atkins Nutritionals claim regarding sugar alcohols' limited impact on blood sugar. (*Id.* ¶¶ 30-32.) Plaintiff cites the Diabetes Teaching Center at the University of California, San Francisco, and Dr. Regina Castro of the Mayo Clinic, who both state that sugar alcohols can affect blood sugar levels. (*Id.* ¶¶ 31-32.) Plaintiff thus alleges that "sugar alcohols do impact blood sugar more than a minimal amount, and Atkins' 'Net Carb' count does not assist consumers with tracking carbohydrates that impact blood sugar because it omits sugar alcohols from its equation." (*Id.* ¶¶ 27, 52-53.) Plaintiff also cites to an FDA warning letter issued in 2014, wherein the FDA admonished a company for failing to include maltitol in its Total Carbohydrate count." (*Id.* ¶ 44 (citing Food and Drug Administration Warning Letter ONPLDS 20-01 (June 20, 2001).) Here, however, the exemplar label provided by plaintiff in its Amended Complaint reveals that maltitol, a sugar alcohol, is included in the total carbohydrate amount, but is then subtracted from the total carbohydrate amount, along with fiber, to obtain the Net Carb amount. (*Id.* ¶ 22.)

In the Amended Complaint, plaintiff provides an example of an allegedly misleading label that states that Atkins

Endulge Chocolate Candies have only one gram of Net Carbs. (Id. ¶¶ 21-26.)



***Counting Carbs?**
Atkins Net Carb Count assists you in tracking carbs that impact blood sugar. Fiber and sugar alcohols should be subtracted from the total carbs since they minimally impact blood sugar.

TOTAL CARBS	FIBER	SUGAR ALCOHOLS	
19g	- 4g	- 14g	=

ATKINS
1g
NET CARBS

Nutrition Facts	
Serving Size 1 pack (28g)	
Amount Per Serving	
Calories 110	Fat Cal. 60
% Daily Value*	
Total Fat 7g	11%
Saturated Fat 4.5g	23%
Trans Fat 0g	
Cholesterol <5mg	1%
Sodium 5mg	0%
Potassium 60mg	2%
Total Carbohydrate 19g	6%
Dietary Fiber 4g	16%
Sugars 1g	
Sugar Alcohols 14g	
Protein 1g	1%
Vitamin A 0%	Vitamin C 0%
Calcium 2%	Iron 2%
Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Saturated Fat	Less than 20g 25g
Cholesterol	Less than 30mg 30mg
Sodium	Less than 2,400mg 2,400mg
Potassium	3,500mg 3,500mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g
Protein	50g 65g

★ Sugar Alcohols total includes 0g of glycerin.

INGREDIENTS: CHOCOLATE COATING (MALTITOL, COCOA BUTTER, INULIN, UNSWEETENED CHOCOLATE, WHOLE MILK POWDER, MILK FAT, COCOA POWDER (PROCESSED WITH ALKALI), SOY LECITHIN, VANILLA, NATURAL FLAVORS, SUCRALOSE), MALTITOL, LESS THAN 1% OF PURE VANILLA EXTRACT, CONFECTIONER'S GLAZE, CARNAUBA WAX, BEESWAX, TITANIUM DIOXIDE COLOR, YELLOW 5 LAKE, RED 40 LAKE, BLUE 1 LAKE, BLUE 2 LAKE, YELLOW 6 LAKE, YELLOW 6, GUM ARABIC. FR01
CONTAINS MILK AND SOY.
THIS PRODUCT IS MANUFACTURED IN A FACILITY THAT USES PEANUTS, OTHER TREE NUTS AND WHEAT.

According to plaintiff, the representations made in the labeling pictured above are “identical or substantially similar” to the representations that appear on the Atkins Nutritionals products identified in paragraph 20 of the Amended Complaint. (*Id.* ¶¶ 20, 25.) The nutritional label includes the following categories: calories, fat calories, total fat, saturated fat, trans fat, cholesterol, sodium, potassium, total carbohydrates, dietary fiber, sugars, sugar alcohols, protein, Vitamin A, Vitamin C, Calcium and Iron. (*Id.* ¶ 22.) Additionally, the packaging includes the formula Atkins Nutritionals utilizes to calculate Net Carbs and explains that fiber and sugar alcohols are excluded from the Net Carb number because they minimally impact blood sugar. (*Id.* ¶ 25.) Plaintiff does not allege that

he purchased the Atkins Indulge Chocolate Candies that he provided as an example of a misleading label, and only alleges that he purchased three of the thirty-one food items listed in paragraph 20 of the Amended Complaint. (*Id.* ¶ 52.)

Plaintiff alleges that he believed Atkins Nutritionals' alleged misrepresentations about Net Carbs on its product labels and relied on those representations in deciding to purchase three products sold by Atkins Nutritionals. (*Id.* ¶¶ 55-57.) Specifically, plaintiff alleges that within the two years preceding the filing of the Amended Complaint, plaintiff purchased a Chocolate Chip Cookie Dough Bar, Sweet & Salty Trail Mix, and Chocolate Peanut Candies from a Wal-Mart store in Nassau County, New York. (*Id.* ¶ 52.)

Plaintiff's Amended Complaint asserts three claims: (1) violation of NYGBL § 349; (2) violation of NYGBL § 350; and (3) breach of express warranty. (*Id.* ¶¶ 67-99.) Plaintiff alleges that by including misleading statements in its labeling, Atkins Nutritionals violated NYGBL § 349 which prohibits deceptive and unfair trade practices, and NYGBL § 350, which prohibits false advertising. (*Id.* ¶¶ 67-89.) Plaintiff seeks an injunction to enjoin defendant's alleged deceptive practices in connection with defendant's alleged violation of NYGBL § 349. (*Id.* ¶ 80.) Further, Plaintiff alleges that Atkins Nutritionals breached its express warranty that its

products would conform to Atkins Nutritionals' written promises on its labels that its products "contained minimal 'net carbs' and . . . sugar alcohols contained therein had minimal and effectively no impact on blood sugar," when its products did not have the qualities promised. (*Id.* ¶¶ 92-98.)

II. Legal Standard

"To survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must contain sufficient facts that if accepted as true 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A well-pleaded complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests. *Carson Optical Inc. v. eBay Inc.*, 202 F. Supp. 3d 247, 252 (E.D.N.Y. 2016) (citing *Twombly*, 550 U.S. at 555). A complaint providing only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the court may refer to "documents attached to the complaint as an exhibit or incorporated in it by reference, to matters of which judicial notice may be taken, or to documents

either in plaintiffs' possession or of which plaintiffs had knowledge and relied on in bringing suit." *Brass v. Am. Film Tech., Inc.*, 987 F.2d 142, 150 (2d Cir. 1993) (internal citations omitted); see also *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 1993) (internal emphasis and citation omitted) (clarifying that "reliance on the terms and effect of a document in drafting the complaint is a necessary prerequisite to the court's consideration of a document on a dismissal motion; mere notice of possession is not enough.").

III. Discussion

a. Plaintiff's State Law Claims Relating to Atkins' Quantitative Net Carbs Claims and Its Calculation Method Are Preempted by Federal Law

Defendant argues that plaintiff's claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA") as amended by the Nutrition Labeling and Education Act ("NLEA"). Specifically, defendant contends that 21 U.S.C. §§ 343(q), 343(r), and 343-1(a)(5) together provide for broad and explicit "preemption of non-identical state law requirements" related to nutrition levels and health-related claims, as described in Section 343(r), that are displayed on food products. Plaintiff counters that his claims are not federally preempted because there is a presumption against preemption and Atkins Nutritionals' Net Carbs representations are not nutrient content claims.

Plaintiff further argues that even if the Net Carb

representations were nutrient content claims, plaintiff's NYGBL claims and breach of warranty claim would not be preempted because defendant's representation of "Xg Net Carbs" is false or misleading.

Upon review, and for the reasons explained below, the court finds that plaintiff's NYGBL and breach of warranty claims regarding defendant's use of the phrase "Xg Net Carbs," and defendant's explanation of the calculation method for Net Carbs that subtracts sugar alcohols and fiber from total carbohydrates are preempted. (Am. Compl. ¶ 52.) The court further finds that plaintiff's claims regarding the "Only Xg Net Carbs" statement on labels and the portion of the "Counting Carbs" information box on the label of the Atkins Nutritionals products that discuss the impact of sugar alcohols on blood sugar, are not preempted. (Am. Compl. ¶¶ 53-54.)

i. Preemption Generally

"Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements." *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008). Further, federal requirements that preempt state law requirements also preempt common law duties. *Riegel*

v. Medtronic, Inc., 552 U.S. 312, 324 (2008) (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005)). Where a statute includes an express pre-emption clause, “[the court] do[es] not invoke any presumption against pre-emption but instead ‘focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress’ pre-emptive intent.’” *Puerto Rico v. Franklin California Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016) (citing *Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 594 (2011)); see also *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319–20 (S.D.N.Y. 2017) (“where . . . Congress has expressly manifested its intent to preempt state law, no presumption against preemption arises”). Here, Congress has expressly manifested its intent:

(a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . .

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 U.S.C. 343–1(a)(5).

Plaintiff argues that in the instant case “[the]

court must begin its analysis with a presumption against preemption.” (ECF No. 28, Plaintiff’s Opposition to Motion to Dismiss (“Pl. Opp.”), at 10 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992); *Bates v. Down Agrosciences LLC*, 544 U.S. 431, 449 (2005) (when presented with two plausible readings of an arguably preemptive federal law, courts have “a duty to accept the reading that disfavors pre-emption.”).) *Medtronic*, however, does not address express preemption provisions, like that at issue in the instant case. 518 U.S. at 485. Further, plaintiff overstates the holding of *Bates*, in which the Supreme Court did not hold that there is a universal “duty to accept the reading that disfavors pre-emption,” but rather applied a reading disfavoring preemption when Congress has not manifestly expressed its intention that the federal regulation preempt state law. See 544 U.S. at 449.

Plaintiff cited *Cipollene* for the proposition that courts must begin their analysis with a presumption against preemption when a defendant raises preemption as a defense. 505 U.S. at 518. In *Cipollene*, however, the Supreme Court incorporated a general presumption against preemption as an interpretive tool where a statute did not provide manifest

expression of Congressional intention to broadly preempt state law damages actions. See *Id.* ("In the 1965 pre-emption provision regarding advertising . . . , Congress spoke precisely and narrowly: 'No statement relating to smoking and health shall be required in the advertising of [properly labeled] cigarettes.'")

ii. The Relevant FDCA Provisions and Implementing Regulations

"The Federal Food, Drug, and Cosmetic Act (FDCA) . . . forbids the misbranding of food, including by means of false or misleading labeling." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2233 (2014) (citing §§ 301, 403, 52 Stat. 1042, 1047, as amended, 21 U.S.C. §§ 331, 343). The NLEA, which amended the FDCA, requires labeling of packaged foods, regulates the making of claims about the nutrient content of foods, and expressly preempts state law requirements regarding nutrient content claims. See 21 U.S.C. §§ 343(q), 343(r), 343-1(a)(5). In 21 U.S.C. 343-1(a)(5), Congress established, in relevant part:

[N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt

under section 343(r) (5) (B) of this title.

Further, "The FDA has promulgated comprehensive rules governing nutrition-box information, found at 21 C.F.R. § 101.9 . .

. [which] sets forth further requirements with respect to the nutrients that must be included in the nutrition-facts box.

Fernandez, 2018 WL 280028, at *3. "The FDA's regulations regarding nutrient content claims are found at 21 C.F.R. § 101.13." *Id.* at *5.

1. 21 U.S.C. 343(q): Disclosure of Nutrition Information

Section 343(q) requires that food labels include certain nutrition information on their labels. Section 343(q) (1) (D) states that foods manufactured and packaged for sale must be labeled to indicate the amount of nutrients contained in the food, including "[t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure." 21 U.S.C. § 343(q) (1) (D); 21 C.F.R. § 101.9(c) (6). Further, "Section 343(q) (2) empowers the Food and Drug Administration ("FDA") with the ability to add nutrients to (or remove nutrients from) the [the list in] § 343(q) (1) [(D)]'s list." *Fernandez*, 2018 WL 2128450, at *4 (citing 21 U.S.C. § 343(q) (2)).

Section 101.9(c) sets forth further requirements with

respect to the nutrients specified in § 343(q) (1) (D) that must be included in the nutrition-facts box on a package of food. Relevant to the instant case, “§ 101.9(c) (6) requires that food labels include . . . a statement of the number of grams of total carbohydrate in a serving, and a statement of the number of grams of total dietary fiber in a serving.”

Fernandez, 2018 WL 2128450, at *4. Dietary fibers and sugar alcohols are considered carbohydrates for the purpose of calculating “total carbohydrates,” and the FDA provides extensive guidance regarding the treatment of sugar alcohols. 21 C.F.R. § 101.9(c) (6) (i)-(iv). Disclosure of sugar alcohols and their weights in the nutrition facts panel of a label is voluntary, however, if a claim is made about the grams of sugar alcohol on the label, disclosure must be made in accordance with 21 C.F.R. § 101.9(c) (6). Section 101.9(c) (6) (iv) states: “[a] statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or total sugars, or added sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared.” 21 C.F.R. § 101.9(c) (6) (iv); see also *Fernandez*, 2018 WL 2128450, at *4.

2. 21 U.S.C. 343(r): Nutrient Content Claims

Section 343(r) (1) governs any voluntary nutrient content claim made in the label or labeling of the food which

expressly or impliedly:

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

21 U.S.C. 343(r); see also *Chacanaca v. Quaker Oats Co.*, 752

F. Supp. 2d 1111, 1117 (N.D. Cal. 2010). Express nutrient

content claims are governed by 21 C.F.R. § 101.13(i)(3).

Under § 101.13(i)(3), "the label or labeling of a product may

contain a statement about the amount or percentage of a

nutrient if ... [t]he statement does not in any way

implicitly characterize the level of the nutrient in the food

and *it is not false or misleading in any respect.*"

Fernandez, 2018 WL 2128450, at *5 (citing § 101.13(i)(3))

(emphasis added). Under § 101.13 (c), "[i]nformation that is

required or permitted by § 101.9 or § 101.36, as applicable,

to be declared in nutrition labeling, and that appears as

part of the nutrition label, is not a nutrient content claim

and is not subject to the requirements of this section."³

Thus, "A nutrient content claim governed by § 343(r)(2) is .

³ Section 101.36 governs the nutrition labeling of dietary supplements. 21 C.F.R. § 101.36.

. .any claim outside of the nutrition-facts box that the manufacturer has chosen to make about the same kind of nutrients discussed inside the . . . nutrition information box.” *Id.*

3. 21 U.S.C. 343-1(a)(5): Express Preemption Relating to Nutrient Content Claims

Section 343-1(a)(5) provides the NLEA’s express
preemption provision:

(a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—
(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 U.S.C. 343-1(a)(5). A requirement is “not identical” to those under Section 343(r) if, “the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] (i) [a]re not imposed by or contained in the applicable provision (including any implementing regulation); or (ii) [d]iffer from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section [341] or [343] of the act.” 21 C.F.R. § 100.1(c)(4); *see also Fernandez*, 2018 WL 2128450, at *5 (citing *Reid v. Johnson &*

Johnson, 780 F.3d 952, 959 (9th Cir. 2015)). "In other words, [plaintiff's] state law claims are not preempted so long as they "effectively parallel[] or mirror[] the relevant sections of the NLEA." *Fernandez*, 2018 WL 2128450, at *5 (citation omitted).

iii. Atkins Nutritionals' "Xg Net Carbs" and "Only Xg Net Carbs" Statements Are Nutrient Content Claims.

Plaintiff argues that Atkins Nutritionals' statements regarding Net Carbs are not "nutrient content" claims, and thus preemption does not apply to them. He is wrong as a matter of established law. Any voluntary statement "made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by" Section 343(q)(1) or (q)(2) is a nutrient content claim governed by Section 343(r). 21 U.S.C. § 343(r); see also *Johnson*, 2017 WL 6420199, at *5 (citing 21 C.F.R. § 101.13(b)(1)). These statements are referred to as nutrient content claims, and may be express claims or implied claims. "An express[] nutrient content claim is any direct statement about the level (or range) of a nutrient in a food." *Johnson*, 2017 WL 6420199, at *5 (internal quotations omitted) (citing 21 C.F.R. § 101.13(b)(1)). An implied nutrient content claim is "any claim that describes the food or an ingredient therein in a manner that suggests that a nutrient

is absent or present in a certain amount (e.g., 'high in oat bran')." *Id.* (citing 21 C.F.R. § 101.13(b)(2)(i)).

Plaintiff's argument that Section 343(q) of the NLEA and its implementing regulations, do not specifically list Net Carbs as a nutrient nor require the inclusion of Net Carbs in the Nutrition Facts panel is unavailing. The broad language in Section 343(r)(1) includes claims regarding nutrients, and relationships of nutrients, "of the type" required by paragraph (q)(1) or (q)(2), obviating the need for specific categorical references to nutrients and nutrient relationships similar to those enumerated in (q)(1) or (q)(2). *See, e.g., Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014) (holding that claims concerning the amount of "antioxidants" present in a beverage were nutrient content claims although "antioxidants" are not nutrients specifically enunciated in Section 343(q)(1) or (q)(2)). Further, Plaintiff essentially alleges that the net carb calculation is a nutrient content claim in the Amended Complaint:

Additionally, Atkins uses the phrase "Only Xg Net Carbs" in its labeling on products identified in paragraph 20. Atkins' use of the term "Only" implies a claim concerning the nutrients of Atkins' products, and improperly suggests that nutrients (i.e. "net carbs") are *absent or present in a certain amount*. Because the FDA has not defined what constitutes an acceptable level to bear the label "Only" in the context of net carbs, Atkins' labels bearing that term are misbranded.

(Am. Compl. ¶ 50 (emphasis added).)

The court in *Fernandez* concluded that Atkins Nutritionals' "Xg Net Carbs" claims were express nutrient content claims because, "they are statements about the amount of nutrients in a product, and those nutrients were of the type required to be discussed by 21 U.S.C. § 343(q)(1) and (q)(2)." *Fernandez*, 2018 WL 2128450, at *5. The court held that the Net Carbs formula calculation was also a nutrient content claim because, "the formula statements discuss the same the type of the same nutrients (total carbohydrates, fiber, and sugar alcohols) in Atkins's products." (*Id.*)

In *Johnson*, the court specifically considered whether Atkins Nutritionals' "Xg Net Carbs" and "Only Xg Net Carbs" statements were express nutrient content claims, and found that "Xg Net Carbs" was an express nutrient content claim and "Only Xg Net Carbs" was an implied nutrient content claim. *Johnson*, 2017 WL 6420199, at *6-7; see also *Smith v. Atkins Nutritionals*, No. 18-CV-04004, ECF No. 35-1, at 9. The FDA appears to concur, and stated, in a warning letter to another manufacturer, that a label stating a food item contained "Only 2g Digestible Carbs" was an "unauthorized nutrient content claim." (Ankrom Dec. Ex. A, FDA Warning Letter to Today's Temptations, Inc., at 2 (March

25, 2010).⁴⁵

iv. State Law Claims Relating to Atkins Nutritionals' Quantitative Net Carbs Claims and Calculation Methods Are Preempted Because "Net Carbs" Nutrient Content Claims Are Not Prohibited Under Federal Law

Defendant correctly argues that state law claims are preempted when they seek to prohibit labeling that is either permitted under federal law or not prohibited under federal law. *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375-376 (S.D.N.Y. 2014) (dismissing preempted state law claims and explaining: "for plaintiffs to establish that their state law claims are not preempted, it is insufficient to show that the FDA has not permitted the label 'Restores Enamel.' Rather, plaintiffs would need to plead facts suggesting that the FDA has affirmatively *prohibited* the label. Otherwise, plaintiffs' state law causes of action would be, in effect, imposing a labeling requirement that is 'not identical with' labeling requirements under federal law."). This is consistent with the regulatory guidance issued by the FDA, which states:

[A] State may not establish or continue in effect any

⁴ District courts may take judicial notice of public records of the FDA on a motion to dismiss. See e.g., *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016) (taking judicial notice of FDA guidance document on motion to dismiss "because the Guidance is publicly available and its accuracy cannot reasonably be questioned" (citations omitted)); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 401 n.2 (S.D.N.Y. 2013) ("For the purpose of resolving the present motion [to dismiss], the Court takes judicial notice of public records contained on the FDA website.").

⁵ Citations to Exhibits in the Ankrom Declaration refer to the internal pagination in the exhibits, and not the page numbers assigned by ECF.

requirement 'of the type' set forth in the sections of the act specified in section [343-1](a)(2) through (a)(5) [,] [t]hus, State or local requirements can be preempted under section [343-1](a)(2) through (a)(5) even if no analogous Federal regulation had been promulgated.

(Ankrom Dec. Ex. B, State Pet. Req. Exemption from Fed.

Preemption, 58 Fed. Reg. 2462-01, at 2463, 1993 WL 1545 (Jan. 6, 1993).) ⁶

Plaintiff has not pleaded sufficient facts to suggest that the FDA has affirmatively prohibited defendant's Net Carbs statements under the FDCA and the NLEA. Rather, there is significant evidence in the public record that Atkins Nutritionals' Net Carbs statements have been directly considered by the FDA, and the FDA has declined to prohibit

⁶ Dismissal of plaintiff's NYGBL claims regarding "Xg Net Carbs" statements on labels and Net Carbs calculations is also required under the safe harbor provisions of §§ 349(d) and 350-d, which state, respectively:

[I]t shall be a complete defense that the act or practice is, or if in interstate commerce would be, subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States as such rules, regulations or statutes are interpreted by the federal trade commission or such department, division, commission or agency or the federal courts.

And,

[I]t shall be a complete defense that the advertisement is subject to and complies with the rules and regulations of, and the statutes administered by the Federal Trade Commission or any official department, division, commission or agency of the state of New York.

NYGBL §§ 349(d), 350-d; see also *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (citation omitted) (Dismissing NYGBL claims under §§ 349(d), 350-d because the label did not violate FDA standards and explaining that "Although § 350-[d] refers only to regulations administered by the Federal Trade Commission ("FTC"), the New York courts have construed that statute to cover regulations by other federal agencies as well").

them. In 2004, the FDA stated it "intend[ed] to initiate rulemaking proceedings for nutrient content claims for carbohydrates . . . [and to] provide guidance to food manufacturers on the use of the term 'net' in relation to the carbohydrate content of food." (Ankrom Dec. Ex. D, FDA Fact Sheet on Carbohydrates, (Mar. 12, 2004).) Shortly thereafter, the FDA received a petition asserting that food manufacturers like Atkins Nutritionals should be able to state the "net" amount of carbohydrates after fiber and the non-caloric portion of sugar alcohols are subtracted from the total carbohydrate figure. (Ankrom Dec. Ex. C, "Nutrient Content Claims," submitted by Unilever United States, Inc., at 1-2 (April 16, 2004).) The FDA issued a statement later that year indicating:

The agency has not generally objected to the use of 'net carbohydrate' type information on food labels if the label adequately explains how the terms are used. If [the] FDA determines that such statements or their explanations are false or misleading, we will take appropriate action. [The] FDA also expects to address this issue in its rulemaking on carbohydrate labeling.

(Ankrom Dec. Ex. E, Ltr. From L. Crawford, Acting FDA Commissioner to NCL (Nov. 19, 2004); see also Ankrom Dec. Ex. H, Ltr. From M. Landa, Deputy Director for Regulatory Affairs, FDA Center for Food Safety and Applied Nutrition, at 1 (Sept. 15, 2005) (FDA letter responding to Unilever inquiry about Atkins Nutritionals' "Net Atkins Count" claims and Net Carbs generally, and stating that it did not generally object to

quantitative net carbohydrate statements, "that are truthful and not misleading, for example where the 'net' terms are sufficiently explained on the label so that the consumer understands the meaning of the use of such terms").) In 2014, the FDA evaluated and responded to comments regarding the calculation of Net Carbs, and declined to expressly prescribe or prohibit a specific formula for calculation of Net Carbs. (See Ankrom Dec. Ex. F, FDA Proposed Rule re Food Labeling, submitted for comment, at 11900 (Mar. 3, 2014); Ankrom Dec. Ex. G, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," Final Rule at 33794-95, cmt. 121 (May 27, 2016).)

In contrast, the FDA has issued warning letters to other companies making what it considered to be false or misleading Net Carbs statements. (See, e.g., Ankrom Dec. Ex. I, Ltr. To Bob's Red Mill Natural Foods, at 1 (July 31, 2012); see also Ex. J, Ltr. To Julian Bakery, Inc., at 2 (July 23, 2014).) In its warning letter to Julian Bakery, the FDA explained that upon evaluation of the nutrient content of the bakery's "Net Carb Zero Bread," it found the bakery's quantification of Net Carbs to be inconsistent with the bakery's own stated formula on the label. (*Id.*) Specifically, the FDA warned:

Your Net Carb Zero Bread product is misbranded under

Section 403(a)(1) of the Act in that the label is false or misleading because the label declares "0g Net Carbs," but this statement is inconsistent with the nutrition information for carbohydrates on your product label as well as your stated definition for the term "Net Carbs" on the product label. *Your label defines "Net Carbs" as follows: "Net Carbs: Subtract Fiber from Total Carbohydrates."* According to your product label, the quantity of Total Carbohydrates is 9g and the quantity of Dietary Fiber is 9g, however, the Sugars declaration on your label is 1 gram. Therefore, in accordance with your declaration for Sugars on your product label, the quantity of Total Carbohydrate for your product is actually 10 grams, which is inconsistent with your "0g Net Carbs" statement.

(Id.)

The court in *In re PepsiCo* examined a plaintiff's state law claims alleging that defendant fraudulently misrepresented the source of water on a label by suggesting the water came from a natural spring, rather than a municipal source. *In re PepsiCo Inc.*, 588 F. Supp. 2d at 537. The FDA previously had been asked to define specific water sources like "spring water" and "well water" and declined to do so. *Id.* at 534. The court held that the plaintiff's claims were preempted because they would have imposed a non-identical requirement in a subject area already regulated and contemplated by the FDA, noting that the FDA had issued guidance saying purified water was not required to disclose its source. *Id.* at 537-538

("Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical

requirements."); see also *Bowling*, 65 F. Supp. 3d at 373.

Applying a similar rationale, the court in *Johnson* held, with respect to Atkins Nutritionals "Xg Net Carbs" statements:

In light of the FDA's permissive view towards net carbohydrate nutrient content claims, the Court finds no violation of Section 343(r) (1) (A) that would render ineffective Section 343-1(a) (5). That being the case, Plaintiff cannot seek damages on the basis that these labels are false or misleading. *To do so would punish Defendant for using the label in a manner that is consistent with Section 343(r).* Furthermore, *Plaintiff seeks to impose requirements in addition to those imposed by Section 343(r) (1) (A) and the applicable federal regulations.* Plaintiff's complaint would require Defendant to utilize a specific method of calculating net carbohydrates before making a net carbohydrate nutrient content claim. The FDA permits net carbohydrate nutrient content claims so long as the statement is quantitatively true and the method of calculation is disclosed. Plaintiff cannot, through a state law cause of action, prescribe a particular calculation that Defendant must use before making a net carbohydrate nutrient content claim. *Therefore, federal law preempts any attempt by Plaintiff to impose a particular method of calculating net carbohydrates.*

Johnson, 2017 WL 6420199, at *6-7 (emphasis added); see also *Fernandez*, 2018 WL 280028, at *9 (holding, "that federal law does preempt California law to the extent that Fernandez seeks to require Atkins to 'utilize a specific method of calculating net carbohydrates before making a net carbohydrate nutrient

content claim.'") (quoting *Johnson*, 2017 WL 6420199, at *7); see also *Smith*, 18-CV-4004, ECF No. 35-1 at 12 (finding plaintiff's claims regarding its calculation method preempted and explaining, "[t]he FDA does not impose a particular method of calculating net carbohydrates[and]. . . an attempt to use a state law cause of action to impose . . . or to prohibit a particular calculation method, would be to impose a requirement different from, or in addition to, those already imposed by federal law."⁷

Thus, it is the case here, as it was in *Bowling*, *Johnson*, *Fernandez* and *Canale*, that, "while the FDA may not have considered the exact language addressed . . . , it had clearly addressed the substance of the claims at issue." *Canale*, 258 F. Supp. 3d at 322-23 (S.D.N.Y. 2017) (citations omitted) (holding that plaintiff's claims were not preempted as the claims based on state law were identical to the provisions of the FDA).

The FDA has: (1) promulgated specific regulations on carbohydrates and sugar alcohols and calculating their weights; (2) been aware of Atkins Nutritionals' Net Carbs calculation

⁷ Smith distinguished between Atkins Nutritionals Net Carbs statements and the representations about blood sugar levels in the "Counting Carbs" labels and held: "Plaintiff's claims may proceed as to the 'Counting Carbs?' labels, which went unchallenged in this Motion to Dismiss, [f]urthermore, Plaintiff may pursue claims that the '___g Net Carbs' labels are misleading on the basis that the explanation provided by the 'Counting Carbs?' label is itself misleading." *Smith*, 18-CV-04004, ECF No. 35-1 at 14.

method, and that it subtracts fiber and sugar alcohols from the total carbohydrates based on an alleged minimal impact on blood sugar; (3) issued warning letters to other manufacturers based on product labels with false, misleading or unexplained Net Carbs statements; and (4) has not opened any enforcement action against Atkins for its Net Carbs statements or promulgated additional requirements concerning them. Taken together, these facts show that the Net Carbs statements are permitted, and therefore a state action challenging them is preempted.

The portion of plaintiff's claims based on Atkins Nutritionals' calculation of Net Carbs and the resulting quantitative statements, such as "1g Net Carb," are preempted and are dismissed. *See Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 WL 5256988, at *6 (S.D.N.Y. Sept. 9, 2015) (quoting *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015)) ("[T]he FDA was given a specific invitation to regulate slack-fill in foods, drugs, and cosmetics, but chose to regulate only slack-fill in foods [T]his is sufficient to bar Plaintiffs' claims: A state rule forbidding non-functional slack-fill in drugs and cosmetics would impose a requirement that is in addition to or not identical with federal law, and it would do so on a subject matter that clearly could be regulated by the FDA [E]ven under the more lenient approach. Plaintiffs' claim still fails.

The FDA's failure to regulate in this area constitutes strong evidence that the FDA considered the issue of slack-fill in drugs and cosmetics and decided that slack-fill in those products is insufficiently misleading to warrant regulation.")

v. State Law Claims Relating to Atkins Nutritionals' Use of The Phrase "Only Net Carbs" and Statement That Sugar Alcohols Minimally Impact Blood Sugar Are Not Preempted

Atkins Nutritionals' use of the term "Only Xg Net Carbs", an implied nutrient content claim, is not preempted. An implied nutrient content claim suggests to consumers that a nutrient is present in a certain amount. 21 C.F.R. § 101.13(b)(2)(i). The FDA is the "sole arbiter" of what is considered a "low" or "high" quantity of a nutrient in a food and sets definitions for certain nutrient quantities. See, e.g., 21 C.F.R. § 101.61. A party may only use an implied nutrient content claim if the product meets the requirements to make the claim. (See Ankrom Dec. Ex. A, FDA Warning Letter, (March 25, 2010) (letter warning manufacturer that the phrase "Only 2g Digestible Carbs" was "an unauthorized nutrient content claim[,] [as the] FDA had not defined th[e] claim for use on food products.")) The FDA has not defined the term "low carbohydrate," and use of the term "only" in "Only Xg Net Carbs" may imply that the product is a low carbohydrate food. See 21 C.F.R. § 101.13 (i)(2)).

[T]he label or labeling of a product may contain a statement about the amount or percentage of a nutrient if: [t]he use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not 'low' in or a 'good source' of the nutrient, such as 'only 200 mg sodium per serving, not a low sodium food.'")

See 21 C.F.R. § 101.13 (i)(2). As Atkins Nutritionals uses the term "only" on certain food labels without qualifying it to clarify that the foods bearing those labels are not "low carbohydrate" foods, the foods may be misbranded under Section 343(r).

Plaintiff's claims, based on the allegation that Atkins Nutritional' labels falsely or misleadingly state that sugar alcohols minimally impact blood sugar, are not preempted. In *Fernandez*, the court found that that the plaintiff's claim that Atkins Nutritionals falsely stated that sugar alcohols "minimally impact blood sugar," was not preempted as the complaint plausibly alleged that scientific evidence contradicted the defendant's claims. See *Fernandez*, 2018 WL 2128450, at *7. The court in *Johnson* also found that the claims regarding the impact of sugar alcohols on blood sugar were not preempted, explaining that the statement is outside the scope of Section 343(r), and its associated regulations. *Johnson*, 2017 WL 6420199, at *8.

Defendant's statement in its "Counting Carbs"

information box regarding the impact of sugar alcohols on blood sugar levels is not a nutrient content claim. It is neither a quantitative statement about sugar alcohols, nor does it imply that sugar alcohols are present in the labeled items in a certain amount. See 21 C.F.R. §§ 101.13(b)(1), 101.13(b)(2)(i). As such, it does not fall under the regulation for nutrient content claims or other health related claims in 21 U.S.C. § 343(r), and is thus outside the preemption provision of 21 U.S.C. § 343-1(a)(5).

**b. Plaintiff's Claims Under the
Doctrine of Primary Jurisdiction**

Defendant seeks to dismiss the action under the doctrine of primary jurisdiction because the claims relate to food labeling, an area explicitly regulated by the FDA. (ECF No. 27-1, Def. Mem., at 25.) Plaintiff argues that primary jurisdiction is inapposite, as (1) the claims relate to the misleading nature of the labeling, a question properly within the realm of judicial decision-making, and (2) the claims do not raise questions that require technical or specialized expertise that Congress committed to a regulatory agency. (Pl. Opp. at 19.) Assuming, arguendo, that plaintiff's claims are not preempted under the FDCA and NLEA, plaintiff's claims should be dismissed under the doctrine of primary jurisdiction, except with regard to plaintiff's claims regarding the "Only Xg

Net Carbs" statements on the label and plaintiff's claims regarding defendant's statement that sugar alcohols minimally impact blood sugar.

The doctrine of primary jurisdiction seeks to "promot[e] proper relationships between the courts and administrative agencies charged with particular regulatory duties." *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (citation and internal quotation marks omitted); see also *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956); *Darbari v. Lenox Hill Hosp., Inc.*, 2011 WL 1226269, at *2-3 (S.D.N.Y. Mar. 24, 2011). Primary jurisdiction applies when "enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956). When determining whether the doctrine of primary jurisdiction applies, courts in the Second Circuit typically consider four factors:

(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.

Ellis, 443 F.3d at 82-83. The doctrine of primary jurisdiction

has a narrow scope and only applies when the issues raised fall outside the "traditional realm of judicial competency." *Goya Foods, Inc. v. Tropicana Prods., Inc.*, 846 F.2d 848, 851 (2d Cir. 1988). As such, application of the primary jurisdiction doctrine "should generally be reserved for resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *King v. Time Warner*, 113 F. Supp. 3d 718, 724 (S.D.N.Y. 2015) (internal quotations marks omitted).

Upon consideration of plaintiff's claims and application of the four factors, primary jurisdiction applies with regard to plaintiff's Net Carbs figures and calculations, and the "Only Xg Net Carbs" statements, as "[i]t is clear that it is the FDA's role to decide what calculation methods manufacturers may use, not the courts." *Johnson*, 2017 WL 6420199, at *9. Primary jurisdiction does not apply to plaintiff's claims as to whether the labeling statements on the impact of sugar alcohols on blood sugar are false or misleading, as that is a factual issue within the traditional real of judicial competency.

*i. Technical Experience of Agency Versus
Conventional Experience of Judge*

Plaintiff argues that determining whether label statements are misleading under consumer protection laws is an

issue within "the conventional experience of judges," and, "is not a technical area in which the FDA has greater technical expertise than the courts." *United States v. Western Pac. R.R. Co.*, 352 U.S. 59, 64 (1956); see *Lockwood*, 597 F. Supp. 2d at 1035. Further, plaintiff argues, numerous courts that have reviewed state law claims based on misleading or deceptive food labels on FDA regulated products have declined to apply the doctrine. See *Ackerman v. Coca-Cola Co.*, No. 09-CV-395, 2010 WL 2925955, at *14 (E.D.N.Y. July 21, 2010) (citation omitted) ("The question whether defendants have violated FDA regulations and marketed a product that could mislead a reasonable consumer is one courts are well-equipped to handle, and is not an appropriate basis for invoking the primary jurisdiction doctrine.") Defendant argues that the FDA's extensive experience enacting rules regarding carbohydrate calculations and the disclosures of dietary fiber and sugar alcohol provide special technical expertise in the area.

The FDA extensively regulates food labeling and has promulgated rules regarding the precise types of nutrient content claims and disclosure requirements implicated by plaintiff's claims. As explained in the discussion of preemption, the FDA has enacted specific rules regarding (1) total carbohydrate calculations, and (2) the disclosure of dietary fibers, sugar alcohols, and their weights. See Section

III.a., *supra*. As discussed in Section III.a, *supra*, the FDA has reexamined those rules in response to petitions regarding Net Carbs statements, and specifically stated that it did not “generally object” to the use of “net carbohydrate” information on food labels as long as the labels “adequately explain[] how the terms are used so that it would not be false or misleading to consumers” and has since declined to impose specific formulas for calculating Net Carbs. See, e.g., Ankrom Dec. Ex. E, Letter From L. Crawford, Acting FDA Commissioner to NCL (Nov. 19, 2004); see also Ankrom Dec. Ex. K (Notice, 70 Fed. Reg. 18032-01, 2005 WL 779201, at 2-3 (Apr. 8, 2005)) (requesting public comment on claims made on food labels, including about net carbs); Ankrom Dec. Ex. L. Notice, 70 Fed. Reg. 48423-01, 2005 WL 1957180, at 2 (Aug. 17, 2005)) (notifying OMB of intent to collect information, including about “net carbs” claims); Ankrom Dec. Ex. H, Letter From M. Landa, Deputy Director for Regulatory Affairs, FDA Center for Food Safety and Applied Nutrition, at 1 (Sept. 15, 2005) (responding to a complaint from an Atkins Nutritionals competitor regarding the Net Carbs labeling and advising that it did not generally object to quantitative Net Carb statements where the Net term is sufficiently explained on the label); Ankrom Dec. Ex. M, Ctr. for Food Safety & Applied Nutrition Consumer Studies’ Research 2001-2009, at 5 (studying reactions to carbohydrate content claims including “net carbs”);

Ankrom Dec. Ex. F, FDA Proposed Rule re Food Labeling, Submitted for Comment, at 11900 (Mar. 3, 2014); Ankrom Dec. Ex. G, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," Final Rule at 33794-95, cmt. 121 (May 27, 2016).) As such, the question of what constitutes proper quantitative Net Carb statements and the proper formula for calculating Net Carbs is best reserved for the FDA.

ii. Agency Discretion

Defendant argues that the narrow issues raised by the Amended Complaint fall squarely within the purview of the FDA's regulatory scheme. The three main issues raised by the Amended Complaint are: (1) whether Atkins Nutritionals is permitted to subtract sugar alcohols from total carbohydrates to calculate the Net Carbs displayed on its product labels, (2) whether Atkins Nutritionals should be able to use the word "only" in connection with the Net Carbs calculation, and (3) whether Atkins Nutritionals can include a statement that sugar alcohols minimally impact blood sugar in its explanation of its Net Carbs calculation. The analysis and regulation in connection with Net Carbs calculations involve technical and policy considerations and are both particularly within the agency's discretion and involve technical and policy considerations within the FDA's particular field of expertise. Further, the FDCA expressly authorizes the FDA to assess whether product labels are

deceptive or misleading. See, e.g., *In re KIND LLC "Healthy and All Natural" Litig.*, 209 F. Supp. 3d 689, 695 (S.D.N.Y. 2016) (citation omitted) ("[T]he FDCA empowers the FDA to prohibit labels that are 'false or misleading in any particular.'").

iii. Risk of Inconsistent Rulings

In the context of primary jurisdiction, the threat of inconsistent rulings may emerge when the issue before a court is simultaneously pending before an agency with authority over that same issue. *Ellis*, 443 F.3d at 88. Defendant argues that because Atkins Nutritionals faces lawsuits in at least three jurisdictions that assert claims substantively almost identical to those asserted by the instant Plaintiff, there is a risk that Atkins Nutritionals could face inconsistent, state-law labeling requirements, making it unduly difficult to comply with the regulation scheme the federal statutes contemplate. See, e.g., *Turek v. General Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). Atkins Nutritionals has also presented extensive evidence that the FDA has considered the Net Carbs issues significantly for over a decade. In *Haggag*, the court dismissed plaintiff's claims regarding allegedly misleading food labeling on primary jurisdiction grounds. *Haggag v. Welch Foods, Inc.*, No. 13-CV-0341, 2014 WL 1246299, at *1 (C.D. Cal. Mar. 24, 2014). The court analyzed current FDA regulations and determined that the FDA had evaluated and regulated similar health claims made on

food or beverages, and although it had not regulated the specific claim at issue, regulating the claim would usurp the FDA's interpretative authority. *Id.* at *5. The same principle applies here.

iv. Prior Application to the FDA

Neither party has applied to the FDA regarding this issue. However, numerous parties have made applications to the FDA concerning Net Carbs claims generally, and there has been at least one appeal regarding Atkins Nutritionals' representations and calculation related to a new proposed Net Atkin's Count. (Ankrom Dec. Ex. H, Letter From M. Landa, Deputy Director for Regulatory Affairs, FDA Center for Food Safety and Applied Nutrition, at 1 (Sept. 15, 2005).)

At least three of the four factors weigh in favor of applying the doctrine of primary jurisdiction and dismissing the plaintiff's claims regarding quantitative Net Carbs statements and formulas for calculating Net Carbs. The FDA currently regulates the listing and calculation of the nutrients underlying defendant's Net Carbs calculation. "[F]or a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority." *POM Wonderful*, 134 S. Ct. at 2236. As such, the court should apply primary jurisdiction to

preclude plaintiff's claims regarding quantitative Net Carbs statements and the formula for the Net Carbs calculations included in the "Counting Carbs" portion of the label.

c. Sufficiency of Plaintiff's NYGBL Claims

Assuming arguendo that plaintiff's claims are not preempted or barred by primary jurisdiction, plaintiff's allegations fail to state a claim upon which relief can be granted as plaintiff insufficiently pleaded that defendant's statements were materially misleading or that plaintiff suffered injury, as required under NYGBL Sections 349 and 350. A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Naked assertions and legal conclusions will not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.").

Sections 349 and 350 of the NYGBL prohibit "[d]eceptive acts or practices and false advertising in the conduct of any business." *Dash v. Seagate Tech.* (U.S.)

Holdings, Inc., 27 F. Supp. 3d 357, 360 (E.D.N.Y. 2014) (internal quotations omitted). "To state a claim under [Sections 349 and 350], Plaintiff must adequately allege three elements: (1) the challenged act or practice was consumer-oriented; (2) the act or practice was misleading in a material way; and (3) the plaintiff suffered injury as result of the deceptive act." *Id.* (internal quotations omitted). Further, "with respect to injury, it is well-settled that a consumer is not entitled to a refund of the price of a good or service whose purchase was allegedly procured through deception under Sections 349 and 350 of the New York General Business Law." *Id.* at 361; see also *Servedio v. State Farm Ins. Co.*, 889 F. Supp. 2d 450, 452 (E.D.N.Y. 2012), *aff'd*, 531 F. App'x 110 (2d Cir. 2013) ("Courts have uniformly read *Small* to mean that Section 349 does not entitle a consumer to a refund of the price of a good or service whose purchase was allegedly secured by deception."). Payment of a premium for a product based on inaccurate representations may be sufficient to allege injury under Sections 349 and 350. *Dash*, 27 F. Supp. 3d at 361 (E.D.N.Y. 2014); see also *Jernow v. Wendy's Int'l, Inc.*, No. 07-CV-3971 2007 WL 4116241, at *3 (S.D.N.Y. Nov. 15, 2007) ("Under New York law, a premium could constitute an actual injury compensable under Section 349.").

Plaintiff provides limited detail regarding the

purchases of the three Atkins Nutritionals products that form the basis of the complaint. He fails to allege with specificity where he purchased the products, when he purchased the products, or what he paid for the products. (See Am. Compl. ¶ 52.) Further, plaintiff fails to allege the actual “net carbs” claims of any of the Atkins Nutritionals products he alleges he purchased, and, instead alleges that an “identical or *substantially similar* claim appears” on the product. (*Id.* ¶ 26 (emphasis added).)

Plaintiff’s allegation that the labels on the products he purchased contained false and misleading statements about carbohydrate content and the impact of sugar alcohols on his blood sugar, along with his provision of an exemplar that is “substantially similar,” to the purchased items, is insufficient to plead that plaintiff’s labels were deceptive or misleading in a material way. (*Id.* ¶¶ 26, 55.)

Plaintiff does not allege facts in the Amended Complaint that support his claim that the statement on Atkins Nutritionals’ food labels that sugar alcohols minimally impact blood sugar is false or misleading. Instead, plaintiff pleads that scientific evidence shows that sugar alcohols “are still a form of carbohydrate, and they still affect your blood sugar

levels, if not as dramatically,"⁸ and that sugar alcohols "can increase your blood sugar level." (Am. Compl. ¶¶ 31-32.) These assertions do not contradict Atkins Nutritionals' labels, which state that sugar alcohols minimally impact blood sugar. The Amended Complaint's proposal of an alternate calculation methodology based on extrapolations from analyses of sugar alcohols' energy content or recommendations by a Canadian regulatory body, is also insufficient to plausibly allege that the statement challenged in the complaint violates FDA regulations or is false and misleading. (*Id.* ¶¶ 34-42.)⁹

Plaintiff also failed to adequately plead injury, the third element of his claims under Sections 349 and 350. Plaintiff's allegation that he was damaged by spending money on products he would not have purchased absent Atkins Nutritionals concealing or misleading consumers about certain information is insufficient to allege injury. See *Dash v.*

⁸ The link provided by plaintiff, where the quote about sugar alcohols in Paragraph 31 of the Amended Complaint was allegedly found, no longer displays the noted information. The quoted statement is now found at the following link, Diabetes Teaching Center, *Counting Sugar Alcohols*, <https://dtc.ucsf.edu/living-with-diabetes/diet-and-nutrition/understanding-carbohydrates/counting-carbohydrates/learning-to-read-labels/counting-sugar-alcohols/> (last visited November 19, 2018). The court, however, must accept as true the complaint's well-pleaded facts in a Rule 12(b)(6) motion to dismiss.

⁹ The following link provided by plaintiff to support the statement, "When counting carbohydrates for products made with sugar alcohols, [one should] subtract half of the grams of sugar alcohol listed on the food label from the total grams of carbohydrate," <http://www.diabetes.org/food-and-fitness/food/what-can-i-eat/understandingcarbohydrates/sugar-alcohols.html>, is no longer operative.

Seagate Tech. (U.S.) Holdings, Inc., 27 F. Supp. 3d 357, 360 (E.D.N.Y. 2014).

To sufficiently plead injury, a plaintiff must allege that, "on account of a materially misleading practice, [he] purchased a product and did not receive the full value of [his] purchase." See *Izquierdo v. Mondelez Int'l, Inc.*, No. 16-CV-4697, 2016 WL 6459832, at *7 (S.D.N.Y. Oct. 26, 2016) (citing *Orlander v. Staples, Inc.*, 802 F.3d 289, 302 (2d Cir. 2015)). Injury can be "overpayment or [payment of a] price premium, whereby a plaintiff pays more than [h]e would have but for the deceptive practice." *Id.* (citing *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 288-289 (S.D.N.Y. 2014)). "Simply . . . recit[ing] the word 'premium' multiple times in the[] Complaint does not make Plaintiffs' injury any more cognizable." *Id.*

In the instant action, plaintiff alleged, "Atkins charges a premium for its products and specifically markets them in a premium location of its retailers; thus, Plaintiff and members of the Class paid more than they normally would have for comparable products." (Am. Compl. ¶ 57.) A well pleaded allegation that a plaintiff paid a premium may be sufficient to allege injury, however, plaintiff only conclusorily asserts that Atkins Nutritionals charges a premium for its products and provides no facts regarding what the

premium was, what price he paid for the products, or the price of non-premium products.

In *Izquierdo*, the plaintiff alleged that he purchased mislabeled candy for a "premium price of \$4.29 (or more)" and provided examples of other candy sold at lower prices. The court held that the plaintiff's allegations were insufficient as plaintiff failed to allege he "paid a *higher* price for the Candy than they otherwise would have, absent deceptive acts." *Id.* Further the plaintiff failed to state whether the defendant or another party set the price for the candy. *Id.* Plaintiff in the instant case pleaded far less: plaintiff pleaded no facts to support his assertion that plaintiff paid a premium price. As such, plaintiff's conclusory allegations are insufficient to identify a cognizable injury. Plaintiff, therefore, fails to state a claim for relief under Sections 349 and 350 of the NYGBL.

d. Plaintiff Fails to State a Claim for Breach
of Warranty as Plaintiff Failed to Provide
Notice of the Alleged Breach

"To state a claim for breach of express warranty, a plaintiff must allege that there was an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to the plaintiff's detriment." *Koenig v. Boulder Brands*,

Inc., 995 F. Supp. 2d 274, 289 (S.D.N.Y. 2014) (citation omitted.) To successfully state a claim for breach of warranty, “a buyer must provide the seller with timely notice of an alleged breach of warranty.” *Singleton v. Fifth Generation, Inc.*, No. 5:15-CV-474, 2016 WL 406295, at *12 (N.D.N.Y Jan. 12, 2016) (citing N.Y. U.C.C. § 2-607(3)(a)). Although a minority of New York State cases suggest an exception to the notice requirement in retail sales, the court declines to impose this exception in the instant action, particularly given that the exception appears to be exclusively applied where a party alleges physical, in addition to economic, injury. See *Fischer v. Mead Johnson Labs.*, 41 A.D.2d 737 (2d Dep’t 1973) (plaintiff developed a blood spot in her eye as a result of the alleged breach); *Silverstein v. R.H. Macy & Co.*, 266 A.D. 5 (1st Dep’t. 1943) (plaintiff suffered serious personal injuries as a result of the alleged breach); *Kennedy v. F.W.Woolworth Co.*, 205 A.D. 648 (1st Dep’t 1923) (plaintiff suffered physical injury as a result of the alleged breach). Plaintiff argues that the court should apply the futility notice exception cited in *Johnson*, however, no such exception exists in New York. *Johnson*, 2017 WL 6420199, at *10.

The Amended Complaint makes no allegations and states no facts showing that notice was provided to defendant.

Therefore, plaintiff's breach of warranty claim fails to state a claim on which relief can be granted and is dismissed. See *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) (dismissing the plaintiffs' breach of warranty claims concerning supplement labels for failure to allege notice).

e. Plaintiff Lacks Standing to Seek Injunctive Relief

Defendant argues that plaintiff lacks standing to seek injunctive relief because plaintiff has not alleged a "likelihood of *future or continuing harm*," and actually implies the opposite, that he would not have purchased the goods had he not been misled by their labels. See *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983) (finding that plaintiff lacked standing to seek injunctive relief "[a]bsent a sufficient likelihood that he will again be wronged in a similar way"); *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016); *Pungitore v. Barbera*, 506 F. App'x 40, 41 (2d Cir. 2012) (summary order) (emphasis in original). Defendant argues that, "[t]here is no exception to demonstrating future injury when the plaintiff is pursuing a class action." *Buonasera v. Honest Co.*, 208 F. Supp. 3d 555, 564-65 (S.D.N.Y. 2016) (dismissing request for injunctive relief where the named plaintiff in a putative class action alleging mislabeling on hair care and

body wash products failed to “demonstrate[] a likelihood of future injury”); see also *Chang v. Fage USA Dairy Indus., Inc.*, No. 14-CV-3826, 2016 WL 5415678, at *5, *9 (E.D.N.Y. Sept. 28, 2016) (dismissing request for injunctive relief in labeling class action where one named plaintiff stated that he “would not have purchased the . . . Products” had he known the label was misleading and because plaintiffs “have not alleged that they will purchase the . . . Products in the future”); *Albert v. Blue Diamond Growers*, 151 F. Supp. 3d 412, 418 (S.D.N.Y. 2015) (“In the instant action, Plaintiffs do not have standing to seek injunctive relief because they have not alleged that they will purchase Defendants’ almond milk labeled products in the future”); *In re Edgewell Personal Care Co. Litig.*, No. 16-CV-03371, ECF No. 64 at 38-46 (E.D.N.Y. Sept. 4, 2018). In *Johnson* and *Fernandez* the courts found that the plaintiffs lacked standing to seek injunctive relief because they failed to allege a likelihood of future harm. *Johnson*, 2017 WL 6420199, at *11-12; *Fernandez*, 2018 WL 280028, at *14-15.

Plaintiff argues that there is an exception to the future harm requirement in consumer protection cases. *Belfiore v. Procter & Gamble Co.*, 94 F. Supp. 3d 440, 445 (E.D.N.Y. 2015) (collecting cases). However, plaintiff cites no binding

precedent to that effect and recent cases contradict plaintiff's position. See *Davis v. Hain Celestial Group, Inc.*, No. 17-CV-5191, 2018 WL 1611375, at *8 (E.D.N.Y. Apr. 3, 2018) (stating cases providing an exception to the future harm requirement are "inconsistent with Article III and with Supreme Court and Second Circuit case law"); *Holve v. McCormick & Co., Inc.*, No. 16-CV-6702, 2018 WL 3861406, at *10 (W.D.N.Y. Aug. 14, 2018) (citations omitted) ("By her own admission, however, Plaintiff will purchase the [food] Products in the future only if Defendant alters its branding. Plaintiff therefore lacks standing to seek injunctive relief because she has not demonstrated a real or immediate threat of injury."). As plaintiff made no allegations of future harm, the court finds that plaintiff lacks standing to bring a request for injunctive relief and plaintiff's request for injunctive relief is denied.

IV. Conclusion

For the foregoing reasons, Defendant's Motion to Dismiss Plaintiff's Amended Complaint is granted in part and denied in part as follows: (1) Plaintiff's NYGBL claims are dismissed with prejudice insofar as they relate to the use of the phrase "Xg Net Carbs" while excluding sugar alcohols and the calculation method for determining the amount of Net Carbs. (2) Plaintiff's claim for breach of warranty is also dismissed with prejudice. (3) Plaintiff's NYGBL claims are dismissed

without prejudice insofar as they relate to the use of the phrase "Only Xg Net Carbs," and the portion of the Atkins Nutritionals "Counting Carbs" label that states that sugar alcohols "minimally impact blood sugar."

Plaintiff is granted leave to amend the complaint to replead his NYGBL claims as specified herein. Plaintiff shall file the amended complaint no later than December 28, 2018.

SO ORDERED.

Dated: Brooklyn, New York
December 7, 2018

/s/
KIYO A. MATSUMOTO
United States District Judge
Eastern District of New York